

REMARKS/ARGUMENTS

Claims 1-12 and 16-21 are pending. Claims 13-15 have been cancelled. Claims 20 and 21 have been added. No new matter has been added with this amendment. Support for the amendment can be found at least at page 8 lines 2-10 and lines 21-25 and FIGS. 1-7. In the Office Action, the Examiner rejected claims 1-19 on various grounds. The Applicant responds to each ground of rejection as subsequently recited herein. Reconsideration of this Application and entry of this Amendment is respectfully requested.

Specification and claim objections

The Abstract of the Disclosure was objected to for including the word “invention.” The Abstract has been amended. Claim 15 was objected to for being a copy of claim 12. Claim 15 has been cancelled. Withdrawal of the objections to the Abstract and claim 15 is requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejections, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

A. Claims 11, 12, 15 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,984,964 to Roberts et al., (the Roberts patent).

The Applicant traverses this rejection. The Applicant respectfully asserts that the Roberts patent fails to include each and every element of the Applicant’s invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). *See* MPEP 2131.

Claim 11 has been amended to recite a protective sleeve “wherein the sleeve has a proximal outer diameter that is greater than the inner diameter of an o-ring of a toughy lock, and wherein the proximal outer sleeve can not pass the o-ring of the toughy lock during deployment of the stent assembly.” The Applicant asserts that the Roberts patent fails to disclose, teach, or suggest at least these limitations. At most, the Roberts patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. For at least these reasons, the Roberts patent does not anticipate claim 11 or any claim depending therefrom.

Claims 12 and 18 depend from claim 11 and include all of the limitations of that claim. Thus for at least this reason, claims 12 and 18 are not anticipated by the Roberts patent. Claim 15 has been cancelled. As to Claim 12, the Roberts patent does not teach the diameters listed but instead teach diameters ten times those claimed by the Applicant. For at least this additional reason, the Roberts patent does not anticipate claim 12.

For these reasons, the withdrawal of the rejection of claims 11, 12, 15 and 18 under 35 U.S.C. § 102(b) is respectfully requested.

B. Claims 11, 16 and 17 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,605,109 to Fiedler, (the Fiedler patent).

The Applicant traverses this rejection. The Applicant respectfully asserts that the Fiedler patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(e). *See* MPEP 2131.

Claim 11 has been amended to recite a protective sleeve "wherein the sleeve has a proximal outer diameter that is greater than the inner diameter of an o-ring of a toughy lock, and wherein the proximal outer sleeve can not pass the o-ring of the toughy lock during deployment of the stent assembly." The Applicant asserts that the Fiedler patent fails to disclose, teach, or suggest at least these limitations. At most, the Fiedler patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. For at least these reasons, the Fiedler patent does not anticipate claim 11 or any claim depending therefrom.

Claims 16 and 17 depend from claim 11 and include all of the limitations of that claim. Thus for at least this reason, claims 16 and 17 are not anticipated by the Fiedler patent. For these reasons, the withdrawal of the rejection of claims 11, 16 and 17 under 35 U.S.C. § 102(e) is respectfully requested.

C. Claims 1-4, 11, 13 and 14 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,270,521 to Fischell et al., (the Fischell patent).

The Applicant traverses this rejection. The Applicant respectfully asserts that the Fischell patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). *See* MPEP 2131.

Claim 1 has been amended to recite a system including a protective sleeve and a port to a vessel "the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter."

Claim 11 has been amended to recite a protective sleeve “wherein the sleeve has a proximal outer diameter that is greater than the inner diameter of an o-ring of a toughy lock, and wherein the proximal outer sleeve can not pass the o-ring of the toughy lock during deployment of the stent assembly.”

The Applicant asserts that the Fischell patent fails to disclose, teach, or suggest at least these limitations. At most, the Fischell patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve and further that the proximal end of the sleeve is distal to the port. For at least these reasons, the Fischell patent does not anticipate claims 1 and 11 or any claim depending therefrom.

Claims 2-4 depend from claim 1 and include all of the limitations of that claim. Thus for at least this reason, claims 2-4 are not anticipated by the Fischell patent. Claims 13 and 14 have been cancelled. For these reasons, the withdrawal of the rejection of claims 1-4, 11, 13 and 14 under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03.

- D. Claims 1, 5, 9 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Roberts in view of Fischell

The Applicant traverses this rejection. The Applicants respectfully assert that the Roberts patent and Fischell patent, alone or in combination, fail to disclose, teach, or suggest all the claim limitations of dependent claims 1 and 19. To sustain a rejection under 35 U.S.C. §103(a), all elements of the independent claim, must be taught or suggested.

Claim 1 has been amended to recite a system including a protective sleeve and a port to a vessel “the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter.” As noted above in section C, the

Fischell patent does not teach or suggest all of the claim limitations of claim 1. The Roberts patent does not cure this defect. At most, the Roberts patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. Thus, Roberts in view of Fischell does not teach or suggest all of the claim limitations of independent claim 1.

Claim 19 has been amended to recite a system for treating a vascular condition comprising a catheter, a stent assembly and a protective sleeve removably covering the stent assembly and at least a portion of the catheter, the protective sleeve comprising an inner sleeve and an outer sleeve the inner sleeve coaxial with the outer sleeve, wherein the inner sleeve and the outer sleeve include a longitudinal gap. Neither the Roberts patent nor the Fischell patent teach such a protective sleeve. For at least this reason, claim 19 is patentable over Roberts in view of Fischell.

Claims 5 and 9 depend from independent claim 1 and so include all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the Roberts patent in view of the Fischell patent for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claims 1, 5, 9 and 19 as being unpatentable over the Roberts patent in view of the Fischell patent is respectfully requested.

E. Claims 1, 7 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fiedler in view of Fischell

The Applicant traverses this rejection. To warrant the §103(a) rejection of claims 1, 7 and 8, Fiedler in view of Fischell must teach or suggest all the claim limitations of claims 1, 4-14 and 17.

Claim 1 has been amended to recite a system including a protective sleeve and a port to a vessel “the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter.” As noted above in section C, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. The Fiedler patent does not cure this defect. As noted in section B, above, at most, the Fiedler patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. Thus, Fiedler in view of Fischell does not teach or suggest all of the claim limitations of independent claim 1.

Claims 7 and 8 depend from independent claim 1 and so include all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the Fiedler patent in view of the Fischell patent for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claims 1, 7 and 8 as being unpatentable over the Fiedler patent in view of the Fischell patent is respectfully requested.

F. Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of Sgro

The Applicant traverses this rejection. Claim 6 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicant, therefore, requests the withdrawal of the rejection of dependent claim 6 under § 103(a).

G. Claims 10 and 14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell as a matter of design choice.

The Applicant traverses this rejection. As noted above, Fischell does not teach or suggest a protective sleeve and a port to a vessel “the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter. These limitations, as well as all other limitations of claim 1, are not mere design choices as alleged by the Examiner. Claim 10 depends from independent claim 1 and includes all of the elements and limitations of independent claim 1 and, thus, is allowable for at least the same reasons as those stated above for claim 1. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Claim 14 has been cancelled. Applicant, therefore, requests the withdrawal of the rejection of dependent claims 10 and 14 under § 103(a).

New claims 20 and 21

New claims 20 and 21 depend from claim 19 and include all of the elements of that claim. Thus, claims 20 and 21 are allowable for at least the same reasons as those of claim 19. Support for claims 20 and 21 can be found at least at page 11 line 24 to page 12 line 9 and FIGS. 6 and 6A. Allowance of claims 20 and 21 is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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